Exhibit B

Gynecare

TVT EXACT™

Continence System

ENGLISH

Please read all directions, precautions, and warnings prior to use. Failure to properly follow instructions may result in improper functioning of the devices and/or may lead to injury. These instructions for use provide direction for using the GYNECARE TVT EXACT™ Continence System. This is not a technique manual nor a substitute for appropriate training and experience in surgical technique for correcting Stress Urinary Incontinence. The device should be used only by physicians trained in the surgical treatment of Stress Urinary Incontinence and specifically in the use of the GYNECARE TVT EXACT™ Continence System. These instructions are recommended for general use of the GYNECARE TVT EXACT™ Continence System. Variations in use may occur in specific procedures due to individual technique and patient anatomy.

DESCRIPTION

The GYNECARE TVT EXACT™ Continence System consists of the following sterile, single-use components:

A. GYNECARE TVT EXACT™ Continence System Trocar Sheath / Implant Assembly (See Figure 1):

1. Implant
2. Implant Sheath
3. Trocar Sheath
4. Trocar Sheath Cut-out

The GYNECARE TVT EXACT™ Continence System Trocar Sheath / Implant Assembly consists of one piece of blue (Phthalocyanine blue, color index number 74160) PROLENE™ Polypropylene Mesh (Implant) approximately 1/2 x 18 inches (1.1 x 45 cm), covered by a clear plastic Implant Sheath and held between two white Trocar Sheaths, which are bonded to the Implant and Implant Sheath. PROLENE Mesh is constructed of knitted filaments of extruded polypropylene strands identical in composition to that used in PROLENE™ Polypropylene Nonabsorbable Surgical Sutures. The Implant is approximately 0.027 inches (0.7 mm) thick. This material, when used as a suture, has been reported to be non-reactive and to retain its strength indefinitely in clinical use. PROLENE Mesh is knitted by a process which interlinks each fiber junction.

B. GYNECARE TVT EXACT™ Continence System Trocar (See Figure 2):

5. Trocar Handle
6. Trocar Sheath Lock
7. Trocar Shaft

The GYNECARE TVT EXACT™ Continence System Trocar consists of the stainless steel Trocar Shaft and the plastic Trocar Handle. The Trocar Shaft is designed to fit inside the white Trocar Sheaths on the GYNECARE TVT EXACT™ Continence System Implant / Trocar Sheath Assembly, and is used to position the GYNECARE TVT EXACT™ Continence System Implant in the patient from a vaginal incision up through the abdominal wall.

GYNECARE TVT Reusable Rigid Catheter Guide

(available separately – not included in GYNECARE TVT EXACT™ Continence System)

The GYNECARE TVT Rigid Catheter Guide is a non-sterile reusable instrument intended to facilitate the identification of the urethra and the bladder neck during the surgical procedure. It is inserted into a Foley catheter (recommended size 18 French) positioned in the bladder via the urethra. To facilitate insertion, it can be lubricated with gel.

INDICATIONS

The GYNECARE TVT EXACT™ Continence System is intended to be used as a pubourethral sling for treatment of female Stress Urinary Incontinence, resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The GYNECARE TVT Rigid Catheter Guide is available separately and is intended to facilitate the placement of the GYNECARE TVT EXACT™ Continence System.

INSTRUCTIONS FOR USE

1. The procedure can be carried out under local anesthesia, but it can also be performed using regional or general anesthesia.
2. Before the patient is prepped and draped, she should be placed in the lithotomy position, taking care to avoid hip flexion greater than 60°.
3. Insert an 18 French Foley catheter and leave it to open drainage.
4. At the level of the mid urethra, inject a small amount of local anesthesia submucosally to create a space between the vaginal wall and the periurethral fascia. The extent of dissection required for placement is minimal. Only a small paraurethral incision is required over the mid urethra to position the tip of the Trocar Sheath. Using forceps, grasp the vaginal wall at each side of the urethra. Using a small scalpel, make a sagittal incision no more than 1.5 cm long starting approximately 1.0 cm cephalad from the urethral meatus. This incision will be positioned over the mid-urethral zone and will allow for subsequent passage of the Implant.
5. With a small pair of blunt scissors, make two small paraurethral lateral dissections (approximately 0.5 to 1.0 cm) to accommodate the tips of the Trocar Sheaths.
6. Identify the two Trocar Sheath exit sites, which should be 2–2.5 cm on each side of the midline, immediately above the pubic symphysis (See Figure 3). Either mark these sites or, if desired, place two small 3–4 mm transverse stab incisions at the intended exit site. In order to avoid the inferior epigastric vessels it is important that the intended exit sites be not more than 2.5 cm from the midline. It is important that the exit sites for the Trocar Sheath passages be near the midline and close to the superior aspect of the pubic bone, in order to avoid anatomic structures in the abdomen, inguinal area and lateral pelvic sidewall.
7. If retropubic infiltration of local anesthesia is not performed then consider infiltrating the retropubic space with two injections of normal saline on either side of midline. Starting at the needle exit sites pass an 18 gauge needle along the back of the pubic bone until the tip of the needle touches the endopelvic fascia. As the needle is withdrawn inject 30 to 50 cc. By so doing it opens up the retropubic space to further minimize the risk of bladder puncture during retropubic Trocar passage.
8. Confirm that all urine has been drained from the bladder. Once the bladder is empty, insert the GYNECARE TVT Reusable Rigid Catheter Guide (available separately) into the channel of the 18 French Foley catheter. The handle of the GYNECARE TVT Reusable Rigid Catheter Guide should be fixed around the catheter at its proximal end. The purpose of placing the GYNECARE TVT Reusable Rigid Catheter Guide into the catheter is to allow contralateral displacement of the bladder, bladder neck and urethra away from the tip of the Trocar Sheath as it is passes through the retropubic space.
9. Place the Trocar Shaft inside one of the two white Trocar Sheaths (See Figure 4). Secure the Trocar Sheath to the Trocar Handle by hooking the Trocar Sheath Cut-out onto the Trocar Sheath Lock on the Trocar Handle (See Figure 5). NOTE: Ensure that the Trocar Sheath Cut-out goes completely over the Trocar Sheath Lock and is holding the Trocar Sheath on the Trocar Shaft securely. Be careful not to manipulate the Trocar Sheath appendage hanging past the Trocar Sheath Lock during the procedure, as that may result in the unintended disengagement of the Trocar Sheath Lock.
10. Gently push the tip of the 18 French Foley catheter toward the posterior lateral wall of the bladder opposite to the intended Trocar Sheath passage (See Figure 6). For example, by pushing toward the patient's left side the

bladder will go from a spherical to a spheroid configuration. This moves the bladder away from the back of the pubic symphysis (See Figure 7A and 7B). Additionally, it moves the bladder neck and the urethra to the left as the Trocar Sheath is passed on the patient's right side, thereby minimizing the risk of bladder perforation (See Figure 8A and 8B).

11. Hold the Trocar Handle using your dominant hand. Pass the tip of the white Trocar Sheath that has been mounted on the Trocar Shaft (see Step 8 above), paraurethrally through the urogenital diaphragm at the level of the midurethra. Initial insertion of the device is controlled by using the tip of the index finger of the non-dominant hand, which is placed in the vagina under the anterior vaginal wall, just lateral to the suburethral incision. The curved part of the Trocar Shaft should rest in the palm of the non-dominant hand. (See Figure 9). Pass the Trocar Sheath through the urogenital diaphragm into the retropubic space. During the initial placement into the paraurethral dissected space, the Trocar Sheath tip should be oriented horizontally, i.e. in the frontal plane. During passage through the urogenital diaphragm, lower the Trocar Handle to ensure that the Trocar Sheath Tip passes vertically while staying in close contact to the back of the pubic symphysis. After passage through the urogenital diaphragm resistance to the passage of the Trocar Sheath is significantly reduced once it enters the retropubic space.
12. At this point, the non-dominant hand is moved from the vagina to the suprapubic exit site. The Trocar Sheath tip is guided through the retropubic space staying as close to the back of the pubic symphysis as possible. This is achieved by lowering the Trocar Handle, thereby pressing the Trocar Sheath tip against the back of the pubic bone.
13. During passage through the retropubic space aim the Trocar Sheath tip towards the pre-marked abdominal exit site.
14. Move the Trocar Sheath tip upwards toward the abdominal skin exit sites keeping in close contact with the pubic bone until exiting the skin (See Figure 10). Once the Trocar Sheath tip exits the skin, grasp the exposed Trocar Sheath tip with a clamp. Release the Trocar Sheath from the Trocar Sheath Lock on the Trocar Handle by pushing the Trocar Sheath appendage laterally and off the Trocar Sheath Lock, and carefully withdraw the Trocar Shaft from within the Trocar Sheath. DO NOT PULL the Trocar Sheath up any further.
15. The procedure is now repeated on the patient's other side while repeating steps 9 – 14. NOTE: IN ORDER TO MINIMIZE THE RISK OF BLADDER INJURY, IT IS IMPORTANT THAT THE BLADDER NOW BE DISPLACED TO THE CONTRALATERAL SIDE USING THE MANEUVERS OUTLINED IN STEP 10.
16. Once both white Trocar Sheaths have been passed and before the Implant is pulled into place, remove the 18 French Foley catheter and perform a cystoscopy (70 degree lens recommended).
17. Once bladder integrity is confirmed, gently pull the Trocar Sheaths upward to bring the Implant loosely (i.e. without tension) under the midurethra. Cut the Implant bilaterally close to the connection to the Trocar Sheaths. Adjust the Implant so that leakage is reduced, allowing only a few drops of urinary leakage to occur under stress. For this, use patient feedback, i.e. coughing with a full bladder (approximately 300 mL).
18. Grasp the Implant Sheaths that surround the Implant with clamps, taking care not to grasp the Implant. Then individually remove the Implant Sheaths by gently pulling up on the clamps, away from the abdomen, one at a time. To avoid putting tension on the Implant, a blunt instrument (scissors or forceps) should be placed between the urethra and the Implant during removal of the Implant Sheaths.
19. **NOTE: Premature removal of the sheaths may make subsequent adjustments difficult.**
20. After proper adjustment of the Implant, close the vaginal incision. The abdominal ends of the Implant are then cut and left in the subcutis; do not suture the Implant.
21. Close the skin incisions with suture or surgical skin adhesive.
22. Empty the bladder. Following this procedure, postoperative catheterization is not typically required. The patient should be encouraged to try to empty their bladder 2-3 hours after the operation.

CONTRAINDICATIONS

As with any suspension surgery, this procedure should not be performed in pregnant patients. Additionally, because the PROLENE Mesh will not stretch significantly, it should not be performed in patients with future growth potential including women with plans for future pregnancy.

WARNINGS AND PRECAUTIONS

- Do not use GYNECARE TVT EXACT™ Continence System on patients who are on anti-coagulation therapy.
- Do not perform the GYNECARE TVT EXACT™ Continence System procedure on patients who have a urinary tract infection.
- Users should be familiar with surgical technique for SUI Sling placement and should be adequately trained in implanting the GYNECARE TVT EXACT™ Continence System before employing it. It is important that the Implant be located without tension under mid-urethra.
- Acceptable surgical practice should be followed for the GYNECARE TVT EXACT™ Continence System procedure as well as for the management of contaminated or infected wounds.
- The GYNECARE TVT EXACT™ Continence System procedure should be performed with care to avoid large vessels, nerves, bladder and bowel. Attention to local anatomy and proper passage of the Trocar Sheaths will minimize risks.
- Retropubic bleeding may occur post-operatively. Observe for any symptoms or signs before releasing the patient from the hospital.
- Cystoscopy should be performed to confirm bladder integrity or recognize a bladder perforation.
- The Rigid Catheter Guide should be gently pushed into the Foley catheter so that the catheter guide does not extend into the holes of the Foley catheter.
- When removing the Rigid Catheter Guide, open the handle completely so that the Foley catheter remains properly in place.
- Do not remove the Implant Sheath until the Implant has been properly positioned.
- Ensure that the Implant is placed with minimal tension under the mid-urethra.
- PROLENE Mesh in contaminated areas should be used with the understanding that subsequent infection may require removal of the material.
- The patient should be counseled that future pregnancies may negate the effects of the surgical procedure and the patient may again become incontinent.
- Since no clinical experience is available with vaginal delivery following the GYNECARE TVT EXACT™ Continence System procedure, in case of pregnancy delivery via cesarean section is recommended.
- Post-operatively, the patient is recommended to refrain from heavy lifting and/or exercise (i.e. cycling, jogging) for at least three to four weeks and intercourse for one month. The patient can return to other normal activity after one or two weeks.
- Should dysuria, bleeding, or other problems occur, the patient should be instructed to contact the surgeon immediately.
- All surgical instruments are subject to wear and damage under normal use. Before use, the instrument should be visually inspected. Defective instruments or instruments that appear to be corroded should not be used and should be discarded.
- As with other incontinence procedures, de novo detrusor instability may occur following the GYNECARE TVT EXACT™ Continence System procedure. To minimize this risk, make sure to place the Implant tension-free in the mid-urethral position.
- Do not contact the PROLENE Mesh with any staples, clips or clamps, as mechanical damage to the mesh may occur.
- Do not resterilize the GYNECARE TVT EXACT™ Continence System. Discard opened, unused devices.

ADVERSE REACTIONS

- Punctures or lacerations of vessels, nerves, bladder or bowel may occur during needle passage and may require surgical repair.
- Transitory local irritation at the wound site and a transitory foreign body response may occur. This response could result in extrusion, erosion, fistula formation and inflammation.
- As with all foreign bodies, PROLENE Mesh may potentiate an existing infection. The plastic sheath initially covering the PROLENE Mesh is designed to minimize the risk of contamination.
- Over correction, i.e., too much tension applied to the implant may cause temporary or permanent lower urinary tract obstruction.

ACTIONS

Animal studies show that implantation of PROLENE Mesh elicits a minimal inflammatory reaction in tissues and stimulates the deposition of a thin fibrous layer of tissue that can grow through the interstices of the mesh, thus incorporating the mesh into adjacent tissue. The material is not absorbed, nor is it subject to degradation or weakening by the action of tissue enzymes.

STERILITY

The GYNECARE TVT EXACT™ Continence System is sterile if kept in original, unopened packaging. DO NOT RESTERILIZE. DO NOT REUSE. Do not use if package is opened or damaged. Discard all opened, unused devices.

The reusable GYNECARE TVT Rigid Catheter Guide is supplied separately and is non-sterile. It is to be cleaned and sterilized prior to each use as described below.

INSTRUCTIONS FOR CLEANING GYNECARE TVT Rigid Catheter Guide (available separately)

To ensure the reliability and functionality of the GYNECARE TVT Rigid Catheter Guide, clean the instrument before initial use and after each procedure. The following are suggested manual and automated methods for cleaning the instruments.

Manual Method:

1. Soak the instrument in an enzyme cleaner suitable for stainless steel instruments.
2. Wash in a surgical detergent and disinfecting solution at a temperature of 86°F to 95°F (30°C to 35°C). Remove any contamination from body fluids or tissues using a soft brush.
3. Place the instrument in an ultrasonic bath with fresh detergent solution for approximately 10 minutes or follow the instructions below if using an automatic washing cycle.
4. Rinse thoroughly in a stream of fresh tap water followed by towel drying. The instrument may be treated with instrument lubricant.

Automated Method:

Automatic washing cycles are suitable for stainless steel instruments. One recommended cycle is described below:

- Rinse/Wet Cycle Cold Water – 1 minute
- Wash 176°F (80°C) – 12 minutes
- Rinse Cycle – 1 minute
- Rinse Cycle – 12 minutes
- Final Rinse – 2 minutes
- Rinse with Demineralized water 176°F (80°C) – 2 minutes
- Dry 199.4°F (93°C) – 10 minutes

STERILIZATION RECOMMENDATIONS FOR GYNECARE TVT Rigid Catheter Guide (available separately)

The GYNECARE TVT Rigid Catheter Guide is supplied non-sterile. To sterilize, steam autoclave prior to each use. Steam autoclave at a temperature of 270°F to 284°F (132°C to 140°C) for a minimum of 4 minutes (pre-vacuum). It is the responsibility of the end user to assure sterility of the product when using sterilization process recommended, since bioburden and sterilization equipment will vary.

GYNECARE TVT Rigid Catheter Guide MAINTENANCE

Before each use, inspect the instrument. Check to ensure that the long end which traverses the catheter channel has no sharp edges or burrs.

DISPOSAL

Dispose of the devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste. Please visit http://www.ethicon.com/recycling for more information.

STORAGE

Recommended storage conditions: controlled room temperature and relative humidity (approximately 25°C, 60% RH), keep away from high moisture and direct heat. Do not use after expiration date.

SYMBOLS

Do not reuse/resterilize	Use by — year and month	CE 0086 CE mark and identification number of Notified Body. Product conforms to the essential requirements of the Medical Device Directive 93/42/EEC
See instructions for use	STERILE EO Method of Sterilization – Ethylene Oxide	
REF Catalogue number	LOT Batch number	